K101119

JUN 1 3 2010

Section 5

510(k) Summary

Date Prepared: April 14, 2010 (original)
Date of Addendum: June 10, 2010

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Proprietary Name: syngo® Dosimetrist Workspace v2.7

Common Name: System, Planning, Radiation Therapy Treatment

Classification: 892.5050

Product Code: MUJ

Substantial Equivalence Claimed To:

PRODUCT	Clearance	Claim of Equivalence For:
SIEMENS COHERENCE™ Dosimetrist Workspace v2.2	K061097	The Siemens *syngo*® Dosimetrist Workspace v2.7
SIEMENS *syngo*® CT ONCOLOGY Software Package	K071310	Auto Segmentation using the Random Walker algorithm for automated volume segmentation.
Computerized Medical Systems, Inc. Atlas-Based Auto-segmentation software	K080799	Auto-segmentation using predefined contours based on anatomical libraries as starting points for rapid contouring. Auto-Segmentation is stand-alone application for atlas based segmentation using deformable registration algorithms.
IKOEtech, LLC, IKOEngelo™	K061006	Automatic contour delineation to support the radiotherapy treatment planning process using deformable registration and segmentation.

The *syngo*® Dosimetrist Workspace v2.7 as described in this premarket notification has similar intended use and fundamental scientific technical characteristics as the predicate devices listed above.

Description Summary for the *syngo*® Dosimetrist Workspace:

Technological Characteristics:

The *syngo*® Dosimetrist Workspace v2.7 supports configuration of both a Virtual Simulation [VSIM] and a Treatment Planning System [TPS] called KonRad™. The *syngo*® Dosimetrist Workspace v2.7 is based on the currently cleared SIEMENS COHERENCE™ Dosimetrist Workspace v2.2 and is intended to be marketed as an update. The basic design, safety features and function of the Dosimetrist Workspace v2.7 remain unchanged from their currently cleared intended use and functions.

The *syngo*® Dosimetrist Workspace v2.7 supports the visualization and clinical assessment of the treatment area using a variety of digital images. The VSIM application supports a three dimensional graphical representation allowing for a virtual setup and treatment of the patient without involving the patient. A variety of software tools are supplied to assist in the delineation of structures for rapid contouring plus segmentation tools for beam profiles and placement on target organ(s) or structures prior to the use by the treatment planning function [TPS].

New features for the VSIM module are the Advanced Segmentation application for rapid contouring and segmentation using the Random Walker algorithm. Additionally, the contouring process can be assisted by the use of Model Based Segmentation for the prostate, bladder, rectum and femurs/hips based on anatomical libraries.

The *syngo*® Dosimetrist Workspace v2.7, when configured with the KonRad inverse planning system, is a radiation therapy treatment planning package designed to optimize multi-leaf collimator (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT). The KonRad component uses the defined anatomical structures for the optimization and treatment planning process.

The final treatment plan can be exported to the appropriate delivery equipment such as a medical linear accelerator, and/or record and verify system. The export of the final treatment plan does not activate the radiation therapy delivery equipment, as all information must be verified by the user prior to the initiation of radiation therapy treatment. The approved treatment plan facilitates the delivery of radiation to defined target volumes while sparing surrounding normal tissue and critical organs from excess radiation using the conventional linear accelerator.

Syngo®:

The *syngo*® Dosimetrist Workspace v2.7 software utilizes the *syngo*® software architecture and allows for a standardized graphical user interface across Siemens medical products. The *syngo*® -based software design consists of task cards allowing for a selection of modules of common software applications for image acquisition, reconstruction, post-processing, display, and archiving across the Siemens medical product lines.

General Safety and Effectiveness:

The device labeling contains instructions for use and any necessary cautions and warnings, to provide for safe and effective use of the device.

Risk Management:

Risk management is ensured via a risk analysis, which is used to identify potential hazards and mitigations. These potential hazards are controlled by software means, user instructions,

verification of requirements and validation of the clinical workflow to ensure that the product meets its intended uses. To minimize electrical, mechanical and radiation hazards, SIEMENS adheres to recognized and established industry practice and relevant international standards.

Intended Use:

The intended use of *syngo*® Dosimetrist Workspace is as an accessory to the linear accelerator system to aid and support in the planning of delivery of x-ray photon and electron radiation for the therapeutic treatment of cancer.

The *syngo*® Dosimetrist Workspace v2.7 is a comprehensive oncology workflow software package that allows for both CT simulation as well as inverse radiation therapy treatment planning and optimization to aid in the oncology clinical workflow where indicated. The *syngo*® Dosimetrist workspace is comprised of two major components, the CT Simulation component (VSIM) and the inverse radiation therapy treatment planning component (KonRad) to be used in the creation, modification, evaluation and approval of radiation treatment plans.

The VSIM component permits CT simulation to be performed on the *syngo*® Dosimetrist workstation. The CT scans are imported into the VSIM software component and the user is able to create three-dimensional models of targets and organs. The VSIM application supports the use of automatic contouring and segmentation or a model based segmentation (MBS) library of anatomical regions may be used. The contours and segmentation can be manually adjusted prior to use by the treatment planning system.

Additionally, the user is able to identify the patient isocenter, place treatment beams, and identify beam modifiers (blocks, apertures, and MLCs). The simulation information is then available for radiation treatment planning for dose calculation via the KonRad software component or other treatment planning systems. The plans are then reviewed and approved by the clinician prior to transfer to the delivery system for the actual treatment.

The KonRad software component is intended to optimize multi-leaf (MLC) positions or partial attenuation block shapes for intensity modulated external beam radiation therapy (IMRT). Once the optimization is complete, the dose distribution and dose volume histogram curves are displayed for the user to evaluate. After approval, the results are exported to the delivery equipment, linear accelerator, or record and verify system, for final verification prior to treatment delivery. The KonRad TPS software component allows for efficient inverse radiation therapy treatment planning and optimization.

Basis for Determination of Substantial Equivalence:

The software contained in the *syngo*® Dosimetrist Workspace v2.7 is based on the software architecture of the previously cleared COHERENCE™ Dosimetrist Workspace v2.2 and utilizes the standard graphical interface based on the Siemens proprietary *syngo*® design. The new features contained in the VSIM module i.e. the Advanced Segmentation application for rapid contouring and segmentation and the Model Based Segmentation for the prostate, bladder, rectum and femurs/hips based on anatomical libraries, utilize the previously cleared Random Walker algorithm as described in Section 12, Substantial Equivalence.

The following verification and validation testing and test results provide objective evidence for the determination of Substantial Equivalence to the predicate devices.

Bench Testing:

Bench testing in the form of Unit, Integration and System Integration testing was performed to evaluate the performance and functionality of the new Advanced Segmentation and Model Based

Segmentation features in the VSIM module. All testable requirements in the Software Requirements Specifications (SRS), Sub-System Requirements Specifications (SSRS), and specifically, the Component Requirements Specifications (CRS) for the algorithms and libraries, have been successfully verified and traced in accordance with the Siemens product development process (PDP).

The software verification and regression testing has been performed successfully to meet their previously determined acceptance criteria as stated in the Test Plans.

Non-Clinical Test Results:

Validation of the *syngo*® Dosimetrist Workspace v2.7 has been performed at the System test level on production prototype devices by appropriately trained and knowledgeable test personnel. System level validation and regression testing has been performed successfully, demonstrating that the software meets the acceptance criteria as noted in the system test plans.

Safety Tests:

Siemens has performed specific System tests to verify interoperability for DICOM connectivity within the clinical environment as well as safety tests specifically for the VSIM module.

Testing to Consensus Standards:

The *syngo*® Dosimetrist Workspace v2.7 has been tested to meet the requirements for conformity (where applicable) to the following standards:

- IEC 60601-1-4:1996+ A1: 1999 – Medical Electrical Equipment: Part 1-4: General requirements for Collateral Standard: Programmable Electrical Medical Systems
- IEC 62083:2001 – Medical Electrical Equipment – Requirements for the Safety of Radiotherapy Treatment Planning Systems
- EN 62366:2008 – Medical Devices – Application of Usability Engineering to Medical Devices
- IEC 62304:2006 Medical Device Software – Software Life Cycle Processes
- DICOM Standards

Substantial Equivalence to Predicates:

The verification testing to the software and component requirements, validation of the intended use, and the regression testing to existing Dosimetrist product requirements, is intended to support the claim of substantial equivalence to the currently cleared COHERENCE™ Dosimetrist Workspace v2.2 (K061097).

The addition of the Advanced Segmentation using the Random Walker algorithm (as a Component) have been verified by Unit and Integration testing to meet the Component Requirements Specifications for this feature contained the *syngo*® Dosimetrist Workspace v2.7, therefore, supporting the claim of substantial equivalence to the same Advance Segmentation application contained in the currently cleared *syngo*® CT Oncology software package (K071310).

Additionally, the Advanced Segmentation application has been verified by objective evidence to support the automatic contouring and segmentation function for radiotherapy treatment planning systems (TPS). This evidence forms the basis for substantial equivalence to the currently cleared automatic contouring and segmentation application for TPS system (K061006).

The Model Based Segmentation component has been verified to meet the Component Requirement Specifications and forms the basis for substantial equivalence to the currently cleared Atlas-Based Auto-segmentation product (K080799).

Summary:

In summary, it is SIEMENS' belief that the *syngo*® Dosimetrist Workspace v2.7 update does not introduce any new potential safety risks and is substantially equivalent to, and performs as well as, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Christine Dunbar
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Siemens Medical Solutions USA, Inc.
Oncology Care Systems
4040 Nelson Avenue
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JUN 1 3 2010

Re: K101119
Trade/Device Name: *syngo*® Dosimetrist Workspace v2.7
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ
Dated: April 14, 2010
Received: April 21, 2010

Dear Ms. Dunbar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101119

Device Name: syngo® Dosimetrist Workspace v2.7

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Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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